

# PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year)  
05 April 2000 (05.04.00)

International application No.  
PCT/US99/20344

Applicant's or agent's file reference  
L0461/7040WO

International filing date (day/month/year)  
03 September 1999 (03.09.99)

Priority date (day/month/year)  
04 September 1998 (04.09.98)

Applicant  
PROBST-KEPPER, Michael et al

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
22 February 2000 (22.02.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Olivia RANAIVOJAONA

Telephone No.: (41-22) 338.83.38

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/20344

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61K 38/00, 38/19, 39/00; G01N 33/567; C07K 14/00, 16/24

US CL : Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/93.71, 185.1; 435/7.21; 530/324, 387.1, 388.15, 388.23; 536/23.5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
Please See Extra Sheet.Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Extra Sheet.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 89/06546 A1 (CETUS CORP.) 27 JULY 1989 (27.07.89), see entire document, especially figure 1, nucleotides 229-270 and page 10, lines 26-34.	12-14
X	EP 0 328 061 A2 (OTSUKA PHARMACEUTICAL CO., LTD.) 16 AUGUST 1989 (16.08.89), see entire document, especially figure 2.	12-14
X	WO 89/09223 A1 (ARCH DEVELOPMENT CORP.) 05 OCTOBER 1989 (05.10.89), see entire document, especially claim 8 and figure 3.	1, 11, 13, 14

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier document published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	*T* "X" "Y" "&"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
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Date of the actual completion of the international search

23 NOVEMBER 1999

Date of mailing of the international search report

22 DEC 1999

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

MARIANNE DIBRINO

Telephone No. (703) 308-0196

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/20344

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☒ Claims Nos.: 16  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/20344

## A. CLASSIFICATION OF SUBJECT MATTER: US CL :

424/93.71, 185.1; 435/7.21; 530/324, 387.1, 388.15, 388.23; 536/23.5

## B. FIELDS SEARCHED

Documentation other than minimum documentation that are included in the fields searched:

protein and peptide databases and DNA databases (N\_Geneseq\_36, GenEmbl, A\_Geneseq\_36, PIR\_60, SwissProt\_37, SPTREMBL\_10, EST\*)

## B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

WEST, STN(CAPLUS, MEDLINE, BIOSIS, EMBASE SCISEARCH, USPATFUL),  
ALTM.-CSF, TORF, Tumor associated open reading frame, CSF-1, CSF, colony stimulating factor-1, colony stimulating factor, HLA-B35, treatment, treat, tumor cell, renal cell carcinoma cells

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
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BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
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CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
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CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification<sup>6</sup> :</b> <b>A61K 38/00, 38/19, 39/00, G01N 33/567, C07K 14/00, 16/24</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 00/13699</b> <b>(43) International Publication Date:</b> 16 March 2000 (16.03.00)
<b>(21) International Application Number:</b> PCT/US99/20344 <b>(22) International Filing Date:</b> 3 September 1999 (03.09.99)  <b>(30) Priority Data:</b> 60/099,077 4 September 1998 (04.09.98) US  <b>(71) Applicant (for all designated States except US):</b> LUDWIG INSTITUTE FOR CANCER RESEARCH [CH/US]; 605 Third Avenue, New York, NY 10158 (US).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> PROBST-KEPPER, Michael [BE/BE]; 7459 Avenue Hippocrate, B-1200 Brussels (BE). VAN DEN EYNDE, Benoit [BE/BE]; 7459 Avenue Hippocrate, B-1200 Brussels (BE). BOON-FALLEUR, Thierry [BE/BE]; 7459 Avenue Hippocrate, B-1200 Brussels (BE).  <b>(74) Agent:</b> VAN AMSTERDAM, John, R.; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).	<b>(81) Designated States:</b> AU, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i> <i>With amended claims.</i>	
<b>(54) Title:</b> AN ANTIGENIC PEPTIDE ENCODED BY AN ALTERNATIVE OPEN READING FRAME OF HUMAN MACROPHAGE COLONY-STIMULATING FACTOR  <b>(57) Abstract</b>  The invention provides immunogenic polypeptides derived from an alternative reading frame of macrophage colony stimulating factor. Methods for diagnosis and treatment which involve the polypeptides also are provided.		

Claims

1. An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:5, or a fragment thereof.
- 5 2. An isolated immunogenic polypeptide comprising the amino acid sequence of SEQ ID NO:12, or a functional variant thereof.
3. The isolated immunogenic polypeptide of claim 2 wherein the isolated immunogenic peptide consists of an amino acid sequence selected from the group consisting of SEQ ID  
10 NO:5, SEQ ID NO:9 and SEQ ID NO:12.
4. The isolated immunogenic polypeptide of claim 1 wherein the isolated polypeptide consists of the amino acid sequence of SEQ ID NO:12.
- 15 5. The isolated polypeptide of claim 1 or claim 2 wherein the isolated polypeptide is non-hydrolyzable.
6. The isolated polypeptide of claim 5 wherein the isolated polypeptide is selected from the group consisting of peptides comprising D-amino acids, peptides comprising a  
20 -psi[CH<sub>2</sub>NH]-reduced amide peptide bond, peptides comprising a -psi[COCH<sub>2</sub>]-ketomethylene peptide bond, peptides comprising a -psi[CH(CN)NH]-(cyanomethylene)amino peptide bond, peptides comprising a -psi[CH<sub>2</sub>CH(OH)]-hydroxyethylene peptide bond, peptides comprising a -psi[CH<sub>2</sub>O]-peptide bond, and peptides comprising a -psi[CH<sub>2</sub>S]-thiomethylene peptide bond.
- 25 7. A composition comprising the isolated immunogenic polypeptide of claim 2.
8. The composition of claim 7, further comprising an isolated non-alt.M-CSF tumor rejection antigen peptide or a precursor thereof.
- 30 9. The composition of claim 7, wherein the isolated immunogenic polypeptide comprises the amino acid sequence of SEQ ID NO:12.

10. The composition of claim 9, wherein the isolated immunogenic polypeptide consists of an amino acid sequence selected from the group consisting of SEQ ID NO:5, SEQ ID NO:9, and SEQ ID NO:12.

5 11. An isolated nucleic acid encoding a peptide selected from the group consisting of the polypeptide of claim 1 and the immunogenic polypeptide of claim 2, wherein the isolated nucleic acid, when translated, does not encode M-CSF, a precursor of M-CSF, or a fragment M-CSF.

10 12. The isolated nucleic acid of claim 11, wherein the nucleic acid comprises SEQ ID NO:11.

13. An expression vector comprising the isolated nucleic acid of claim 11 operably linked to a promoter.

15 14. The expression vector of claim 13 wherein the nucleic acid comprises SEQ ID NO:11.

15. The expression vector of claims 13 or 14 further comprising a nucleic acid which encodes an HLA-B\*3501 molecule.

20 16. A host cell transfected or transformed with an expression vector selected from the group consisting of the expression vector of claim 13, the expression vector of claim 14, and the expression vector of claim 15.

25 17. A host cell transfected or transformed with an expression vector selected from the group of the expression vector of claim 11 and the expression vector of claim 12, and wherein the host cell expresses an HLA-B\*3501 molecule.

30 18. A method for enriching selectively a population of T lymphocytes with CD8<sup>+</sup> T lymphocytes specific for an alt.M-CSF immunogenic polypeptide comprising:

contacting an isolated population of T lymphocytes with an agent presenting a complex of the alt.M-CSF immunogenic polypeptide and an HLA class I molecule in an



## AMENDED CLAIMS

[received by the International Bureau on 22 February 2000 (22.02.00);  
original claim 1 amended; remaining claims unchanged (1 page)]

1. An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:5, or a fragment thereof having at least 14 consecutive amino acids of SEQ ID NO:5.
2. An isolated immunogenic polypeptide comprising the amino acid sequence of SEQ ID NO:12, or a functional variant thereof.
3. The isolated immunogenic polypeptide of claim 2 wherein the isolated immunogenic peptide consists of an amino acid sequence selected from the group consisting of SEQ ID NO:5, SEQ ID NO:9 and SEQ ID NO:12.
4. The isolated immunogenic polypeptide of claim 1 wherein the isolated polypeptide consists of the amino acid sequence of SEQ ID NO:12.
5. The isolated polypeptide of claim 1 or claim 2 wherein the isolated polypeptide is non-hydrolyzable.
6. The isolated polypeptide of claim 5 wherein the isolated polypeptide is selected from the group consisting of peptides comprising D-amino acids, peptides comprising a -psi[CH<sub>2</sub>NH]-reduced amide peptide bond, peptides comprising a -psi[COCH<sub>2</sub>]-ketomethylene peptide bond, peptides comprising a -psi[CH(CN)NH]-(cyanomethylene)amino peptide bond, peptides comprising a -psi[CH<sub>2</sub>CH(OH)]-hydroxyethylene peptide bond, peptides comprising a -psi[CH<sub>2</sub>O]-peptide bond, and peptides comprising a -psi[CH<sub>2</sub>S]-thiomethylene peptide bond.
7. A composition comprising the isolated immunogenic polypeptide of claim 2.
8. The composition of claim 7, further comprising an isolated non-alt.M-CSF tumor rejection antigen peptide or a precursor thereof.
9. The composition of claim 7, wherein the isolated immunogenic polypeptide comprises the amino acid sequence of SEQ ID NO:12.

09/786214

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

REC'D 05 JAN 2001

WPC

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference L0461/7040WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/20344	International filing date (day/month/year) 03 SEPTEMBER 1999	Priority date (day/month/year) 04 SEPTEMBER 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant LUDWIG INSTITUTE FOR CANCER RESEARCH		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets.  
☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
These annexes consist of a total of 2 sheets.

- This report contains indications relating to the following items:
  - ☒ Basis of the report
  - ☐ Priority
  - ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
  - ☐ Lack of unity of invention
  - ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain documents cited
  - ☐ Certain defects in the international application
  - ☒ Certain observations on the international application

Date of submission of the demand  22 FEBRUARY 2000	Date of completion of this report  08 NOVEMBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer <i>Dorthea Lawrence Fox</i> MARIANNE DIBRINO
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/20344

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

☐ the international application as originally filed☒ the description:

pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the claims:

pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the drawings:

pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the sequence listing part of the description:

pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig. NONE5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US99/20344

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 16

because:

☐ the said international application, or the said claim Nos. \_ relate to the following subject matter which does not require international preliminary examination (*specify*).

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 16 are so unclear that no meaningful opinion could be formed (*specify*).

Claim 16 is an improper multiple dependent claim because it depends upon another multiple dependent claim.

☐ the claims, or said claims Nos. \_ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/20344

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)

Claims 1-15, 17-64

YES

Claims NONE

NO

Inventive Step (IS)

Claims 1-15, 17-64

YES

Claims NONE

NO

Industrial Applicability (IA)

Claims 1-15, 17-64

YES

Claims NONE

NO

**2. citations and explanations (Rule 70.7)**

Claims 1-15 and 17-64 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed isolated alt.M-CSF polypeptides, nucleic acids encoding said polypeptides, host cells comprising said nucleic acids, antibodies specific for said polypeptides, vaccine compositions and methods of making and using said polypeptides.

Claims 1-15 and 17-64 meet the criteria set out in PCT article 33(4) because the claimed polypeptides, the nucleic acids encoding said polypeptides, the antibodies specific for said polypeptides, vaccine compositions and the methods of the instant invention are useful for induction of immunity towards the said polypeptides which are derived from a tumor associated antigen.

----- NEW CITATIONS -----

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/20344

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 16 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): Claim 16 is an improper multiple dependent claim because it depends upon another multiple dependent claim.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/20344

**Supplemental B x**

(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 10

Continuation of: Boxes I - VIII

**CLASSIFICATION:**

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A61K 38/00, 38/19, 39/00; G01N 33/567; C07K 14/00, 16/24 and US Cl.: 424/93.71, 185.1; 435/7.21; 530/324, 387.1, 388.15, 388.23; 536/23.5

**I. BASIS OF REPORT:**

This report has been drawn on the basis of the description,  
page(s) 1-42, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the claims,  
page(s) 45-51, as originally filed.  
page(s) NONE, as amended under Article 19.  
page(s) 43, filed with the demand.  
and additional amendments:  
Claim page 44, filed with the letter of 29 September 2000.

This report has been drawn on the basis of the drawings,  
page(s) 1-8, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the sequence listing part of the description:  
page(s) NONE, as originally filed.  
pages(s) NONE, filed with the demand.  
and additional amendments:  
NONE

IFD

## PCT

JAN 03 2001

2001  
NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

**(PCT Rule 71.1)**

Initials

*for*

**Date of Mailing**  
(day/month/year)

29 DEC 2000

## IMPORTANT NOTIFICATION

Priority Date (day/month/year)

04 SEPTEMBER 1998

LUDWIG INSTITUTE FOR CANCER RESEARCH

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Authorized officer

MARIANNE DIBRINO

Telephone No. (703) 308-0196

**Facsimile No. (703) 305-3230**



# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

### NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

<b>To: JOHN VAN AMSTERDAM</b> <b>WOLF, GREENFIELD &amp; SACKS, P.C.</b> <b>600 ATLANTIC AVENUE</b> <b>BOSTON, MASSACHUSETTS 02210</b> <b>UNITED STATES OF AMERICA</b>		<b>Date of Mailing</b> <i>(day/month/year)</i> <b>29 DEC 2000</b>	
<b>Applicant's or agent's file reference</b> <b>L0461/7040WO</b>		<b>IMPORTANT NOTIFICATION</b>	
<b>International application No.</b> <b>PCT/US99/20344</b>	<b>International filing date</b> <i>(day/month/year)</i> <b>03 SEPTEMBER 1999</b>	<b>Priority Date</b> <i>(day/month/year)</i> <b>04 SEPTEMBER 1998</b>	
<b>Applicant</b> <b>LUDWIG INSTITUTE FOR CANCER RESEARCH</b>			

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

**4. REMINDER**

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Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

<b>Name and mailing address of the IPEA/US</b> Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 <b>Facsimile No. (703) 305-3230</b>	<b>Authorized officer</b> MARIANNE DIBRINO <i>M. Laurence For</i> <b>Telephone No. (703) 308-0196</b>
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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference L0461/7040WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/20344	International filing date (day/month/year) 03 SEPTEMBER 1999	Priority date (day/month/year) 04 SEPTEMBER 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant LUDWIG INSTITUTE FOR CANCER RESEARCH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  22 FEBRUARY 2000	Date of completion of this report  08 NOVEMBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer <i>Dorthea Lawrence</i> MARIANNE DIBRINO
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/20344

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

☐ the international application as originally filed

☒ the description:  
 pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the claims:  
 pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the drawings:  
 pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the sequence listing part of the description:  
 pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages \_\_\_\_\_ NONE \_\_\_\_\_
- ☒ the claims, Nos. \_\_\_\_\_ NONE \_\_\_\_\_
- ☒ the drawings, sheets/fig \_\_\_\_\_ NONE \_\_\_\_\_

### 5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US99/20344

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 16

because:

☐ the said international application, or the said claim Nos. \_ relate to the following subject matter which does not require international preliminary examination (*specify*).

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 16 are so unclear that no meaningful opinion could be formed (*specify*).

Claim 16 is an improper multiple dependent claim because it depends upon another multiple dependent claim.

☐ the claims, or said claims Nos. \_ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)

Claims 1-15, 17-64

YES

Claims NONE

NO

Inventive Step (IS)

Claims 1-15, 17-64

YES

Claims NONE

NO

Industrial Applicability (IA)

Claims 1-15, 17-64

YES

Claims NONE

NO

**2. citations and explanations (Rule 70.7)**

Claims 1-15 and 17-64 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed isolated alt.M-CSF polypeptides, nucleic acids encoding said polypeptides, host cells comprising said nucleic acids, antibodies specific for said polypeptides, vaccine compositions and methods of making and using said polypeptides.

Claims 1-15 and 17-64 meet the criteria set out in PCT article 33(4) because the claimed polypeptides, the nucleic acids encoding said polypeptides, the antibodies specific for said polypeptides, vaccine compositions and the methods of the instant invention are useful for induction of immunity towards the said polypeptides which are derived from a tumor associated antigen.

✓ ----- NEW CITATIONS -----  
NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 16 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): Claim 16 is an improper multiple dependent claim because it depends upon another multiple dependent claim.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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**Supplemental B x**

(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 10

Continuation of: Boxes I - VIII

**CLASSIFICATION:**

The International Patent Classification (IPC) and/or the National classification are as listed below:  
IPC(7): A61K 38/00, 38/19, 39/00; G01N 33/567; C07K 14/00, 16/24 and US Cl.: 424/93.71, 185.1; 435/7.21; 530/324, 387.1, 388.15, 388.23; 536/23.5

**I. BASIS OF REPORT:**

This report has been drawn on the basis of the description,  
page(s) 1-42, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the claims,  
page(s) 45-51, as originally filed.  
page(s) NONE, as amended under Article 19.  
page(s) 43, filed with the demand.  
and additional amendments:  
Claim page 44, filed with the letter of 29 September 2000.

This report has been drawn on the basis of the drawings,  
page(s) 1-8, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the sequence listing part of the description:  
page(s) NONE, as originally filed.  
pages(s) NONE, filed with the demand.  
and additional amendments:  
NONE